

Application No. 10/612,497
Reply to March 15, 2005 Office Action
Reply Dated April 21, 2005

REMARKS

Applicants have cancelled claims 105-115 and 138-147, without prejudice.

Applicants expressly reserve the right to pursue any cancelled subject matter in subsequent applications that claim benefit from this application. Applicants have amended claims 124, 127, 128, 135, 149, 156, 158, 164 and 165 and have added claims 177-230 to more particularly point out and distinctly claim the subject matter that they wish to prosecute in this application. Applicants also have amended claim 116 to delete the phrase "from said cell" for consistency with the other claims. Upon entry of the amendments, claims 116-137 and 148-230 will be pending.

As described in more detail below, applicants also have amended the specification to correct informalities, to update the priority claim and to insert sequence identification numbers.

None of these amendments adds new matter. Applicants request entry of the amendments and reconsideration of the claims.

Sequence Identifiers

Applicants have amended the specification to insert sequence identifiers where appropriate [37 C.F.R. § 1.821-1.825].

Title

Applicants have amended the title to reflect the subject matter of the pending claims.

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Priority Claim

Applicants have amended the first paragraph of the specification to indicate that US Patent application 09/472,087, from which this application claims priority under 35 U.S.C. § 120, is now U.S. Patent 6,682,736.

February 12, 2004 Information Disclosure Statement

Applicants appreciate the Examiner's acknowledgement of a February 12, 2004 Information Disclosure Statement. The Examiner states that a copy of one of the documents listed thereon, "RE 35,500; Rhodes", could not be located in the file of priority application 09/472,087, and invites applicants to re-submit this document. Accordingly, applicants submit herewith a replacement copy of the document, along with a copy of the previously filed Information Disclosure Statement.

Use of Trademarks

Applicants have amended the specification to denote trademarks in capital letters with accompanying generic terminology.

Informalities

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Applicants have amended the specification to correct informalities, including spelling and other clerical errors.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 127-137 and 164-171 stand rejected under 35 U.S.C. §112, first paragraph, as lacking written description for the language "without the signal sequence". Applicants' deletion of this language objected to (which in any event appears to be redundant) obviates the rejection.

Claims 113, 124, 135, 146 and 156 also stand rejected under § 112, first paragraph, as lacking written description. The Examiner likewise indicates that the rejection is intended as a new matter rejection. The Examiner points out that the claims recite "NS0" cell line while the specification recites "NSO" cell line. Applicants' cancellation of claims 113 and 146, without prejudice, obviates this rejection as to those claims. Applicants believe that reference to "NSO" cells in the specification, for example, on page 49, lines 16-21 and page 68, line 5, fully supports "NS0" in the claims. The indicated cell line is well-known. Because the number zero is alternatively referred to in speech as "zero" or "oh", the cell line referred to here also is interchangeably spoken of as "NS-zero" and "NS-oh". Likewise, the cell line is indicated in writing as both "NS0" and "NSO". However, to expedite prosecution of this application, applicants have conformed claims 124, 135 and 156 to the usage "NSO" in the application, as filed.

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Claims 105 -115 and 138-147 stand rejected under § 112, first paragraph, as not enabled. Specifically, the Examiner is of the view that the identity of the deposit relating to monoclonal antibody 4.1.1 is unclear. To expedite prosecution, applicants have cancelled claims 105-115 and 138-147, without prejudice, thereby obviating the rejection.

Rejection Under 35 U.S.C. § 102(b)

Claims 105-110 and 112 stand rejected under 35 U.S.C. § 102(b) as “anticipated” by Kuchroo et al. (US Patent 6,207,156)(“Kuchroo”). The Examiner alleges that Kuchroo “teaches” humanized monoclonal antibodies that bind to CTLA-4. The Examiner also alleges that Kuchroo “define[s] humanized monoclonal antibodies as human monoclonal antibodies (e.g. column 7 first paragraph and last paragraph).”

Applicants’ cancellation of claims 105-110 and 112, without prejudice, to expedite prosecution of this application, obviates the rejection.

However, applicants wish to note that the first passage pointed to by the Examiner states (column 7, lines 1-5):

A “humanized monoclonal antibody” as used herein is a human monoclonal antibody or functionally active fragment thereof having human constant regions and a CTLA-4 binding CDR3 region *from a mammal of a species other than a human.* (emphasis added).

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As defined by Kuchroo, thus, a "humanized monoclonal antibody" must comprise a non-human CDR3. In contrast, the claimed antibodies are not humanized, and do not comprise a non-human CDR3.

The Examiner also points to the last paragraph in column 7 of Kuchroo which recites in relevant part:

"In preferred embodiments, the humanized antibodies of the invention are human monoclonal antibodies including at least the CTLA-4 binding CDR3 region of the deposited monoclonal antibody."

The "deposited monoclonal antibody" in Kuchroo is a murine antibody. See column 21, lines 18-20 ("Two mouse anti-human CTLA-4 monoclonal antibodies, A3.4H2 and A3.6B10, were identified.") and column 23, lines 44-48 ("Hybridoma A3.4H2 and A3.6B10 were deposited on Mar. 21, 1997, with the American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Va. 20220-2209, as ATCC Accession No. HB-12319 and HB-12318."). Accordingly, as with the first passage relied on by the Examiner, this passage of Kuchroo refers to a monoclonal antibody that must include a non-human CDR3. The claimed antibodies do not. Applicants believe, thus, that the rejection under § 102(b) should in any event be withdrawn.

Rejection Under 35 U.S.C. § 103(a)

Claims 105, 111, 113 and 115 stand rejected under 35 U.S.C. § 103(a) as "unpatentable" over Kuchroo in view of European Patents 0216846 and 0256055 and United States patent

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5,939,598 (Kucherlapati et al.). For the above noted reasons, the primary Kuchroo reference does not support this rejection. Applicants' cancellation of these claims, without prejudice, obviates this rejection.

Double Patenting Rejection

Claims 105-176 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting, as allegedly being unpatentable over claims 1-4, 9-11, 16-17 and 20 of co-pending United States application 10/776,649 ("649 application") in view of United States Patents 5,939,598 (Kucherlapati et al.) and 6,207,156 (Kuchroo et al.) and European Patents 0216846 and 0256055. Applicants stand ready to file a Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c) upon notice that the claims of the '649 application have been allowed.

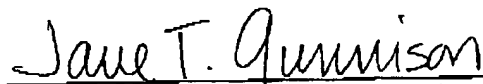
Claims 105-113, 115-124, 126-135, 137-147, 164-169, 171-173 and 175-176 also stand rejected under the judicially created doctrine of obviousness-type double patenting, as allegedly being "unpatentable" over claims 4 and 6 of United States Patent 6,682,736 in view of United States Patents 5,939,598 (Kucherlapati et al.) and 6,207,156 (Kuchroo et al.) and European Patents 0216846 and 0256055. Applicants file herewith two Terminal Disclaimers in compliance with 37 C.F.R. §1.321(c) along with the required fee [37 C.F.R. § 120(d)].

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CONCLUSION

In view of the foregoing, applicants request withdrawal of the rejections and allowance of the claims.

Respectfully submitted,



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